

**Notice of Allowability**

Application No.

10/641,149

Examiner

Hope A. Robinson

Applicant(s)

TOBIN ET AL.

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 1/23/07.
2.  The allowed claim(s) is/are 39-44.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some\*    c)  None    of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  
(a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
    1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.  
(b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
    Paper No./Mail Date 20070920  
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
    Paper No./Mail Date 11/24/03
4.  Examiner's Comment Regarding Requirement for Deposit  
    of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
    Paper No./Mail Date \_\_\_\_\_.  
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

Hope A. Robinson  
Primary Examiner  
Art Unit: 1652

**EXAMINER'S AMENDMENT**

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization of this Examiner's amendment was given in a telephone interview with Ms. Erin Dunston on September 21, 2007 and September 24, 2007.

3. The Claims have been amended as follows:

Claim 39 (Currently amended) An isolated nucleic acid sequence encoding a polypeptide [having an amino acid sequence] consisting of a sequence present in the glutamic acid decarboxylase<sub>65</sub> (GAD<sub>65</sub>) of [Figure 2] SEQ ID NO:5 or [Figure 3] SEQ ID NO:8 and possessing at least one epitope for an autoantibody to GAD<sub>65</sub> wherein said epitope is present in GAD<sub>65</sub> but not in GAD<sub>67</sub>.

4. The Abstract has been amended as follows:

[cDNA molecules coding for GAD<sub>65</sub> polypeptide.] The invention provides cDNA molecules comprising a part of the cDNA sequence of GAD<sub>65</sub> which encode at least one epitope for autoantibodies to GAD<sub>65</sub>. The invention also provides cloning vehicles capable of replication and expression comprising cDNA molecules coding for GAD<sub>65</sub>.

The invention further provides for hosts transformed with a vehicle having a cDNA molecule coding for GAD<sub>65</sub>. In another embodiment, the invention provides for the detection of autoantibodies to GAD<sub>65</sub> using the GAD<sub>65</sub> polypeptides coded for by the cDNA molecules of the invention.

5. The Specification has been amended as follows:

Please replace the present title "Cloned Glutamic Acid Decarboxylase" with the following:  
"Nucleic Acid Encoding GAD<sub>65</sub>".

#### EXAMINER'S COMMENTS

##### ***Information Disclosure Statement***

6. The Information Discloser Statement filed November 24, 2003 have been considered in full and a copy of the PTO-1449 form is attached.

##### ***Withdrawn-Claim Rejections-112***

7. Previous rejections to the claims under 35 U.S.C. 112 first paragraph, is withdrawn by virtue of submission of an amendment and the amendment herein.

##### ***Drawing***

8. The drawings filed on August 15, 2003 are objected to by the examiner, see Figures 6-7, which are dark. It is noted that this application contains drawings executed in color. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color.

Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Correction is required.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

HOPE ROBINSON  
PRIMARY EXAMINER

Primary Examiner

HR  
9/24/0